



APR - 8 2008

A. David Joran
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Legal Division
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New York, NY 10017-5755

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,410,550

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,410,550, which claims the human drug product CHANTIX® (varenicline), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 544 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 544 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of June 7, 2007 (72 Fed. Reg. 31588), would be 799 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,219 \text{ days} - 985) + 182 \text{ days} \\ &= 799 \text{ days (2.2 years)}\end{aligned}$$

Since the regulatory review period began October 15, 1999, before the patent issued (June 25, 2002), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From October 15, 1999, to and including June 25, 2002, is 985 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 799 days, would extend the patent from November 13, 2018, to January 20, 2021, which is beyond the 14-year limit (the approval date is May 10, 2006, thus the 14 year limit is May 10, 2020). The period of extension is thus limited to May 10, 2020, by operation of 35 U.S.C. § 156(c)(3).

Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, November 13, 2018, to and including May 10, 2020, or 544 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

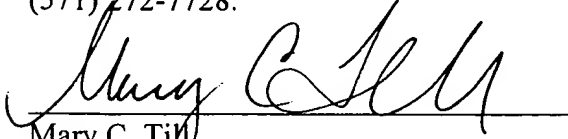
U.S. Patent No.:	6,410,550
Granted:	June 25, 2002
Original Expiration Date ¹ :	November 13, 2018
Applicant:	Jotham Wadsworth Coe, <i>et al.</i>
Owner of Record:	Pfizer Inc.
Title:	Aryl Fused Azapolycyclic Compounds
Product Trade Name:	CHANTIX® (varenicline)
Term Extended:	544 days
Expiration Date of Extension:	May 10, 2020

¹Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7728
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Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.



Mary C. Tiff
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Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: CHANTIX® (varenicline)
FDA Docket No.: 2007E-0010

Attention: Beverly Friedman